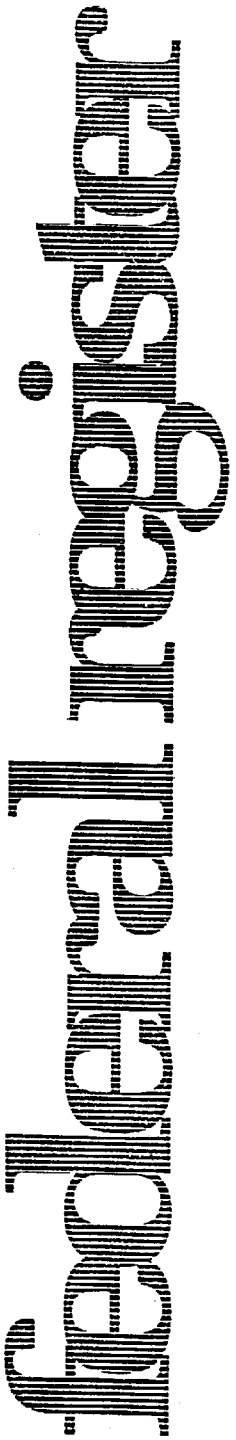

Tuesday
December 21, 1993

Part VII

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 900

Mammography Facilities—Requirements for Accrediting Bodies and Quality Standards and Certification Requirements; Interim Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. 93N-0351]

Requirements for Accrediting Bodies of Mammography Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim rule with request for comments.

SUMMARY: The Food and Drug Administration (FDA) is issuing regulations to implement the Mammography Quality Standards Act of 1992 (MQSA), which requires the establishment of a Federal certification and inspection program for mammography facilities; regulations and standards for accrediting bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. This rule establishes procedures for application to FDA for approval as an accrediting body and requirements and responsibilities of such bodies. This action is being taken to assure adequate and consistent evaluation of mammography facilities on a nationwide level and to help assure their compliance with quality standards. The agency requests comments on the contents of this document.

DATES: These regulations are effective February 22, 1994. Written comments by January 20, 1994.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Charles Showalter, Center for Devices and Radiological Health (HFZ-200), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-3311.

SUPPLEMENTARY INFORMATION: On October 27, 1992, the MQSA (Pub. L. 102-539) was enacted to establish uniform, national quality standards for mammography. The MQSA amends part F of Title III of the Public Health Service Act (the PHS Act) (42 U.S.C. 262 *et seq.*) by adding new section 354 (42 U.S.C. 263b) to establish a comprehensive statutory mechanism for certification and inspection of all mammography facilities in the United States. The MQSA requires that, to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accrediting organization and obtain a certificate from the Secretary of Health and Human Services (HHS) (the Secretary), and, by delegation, FDA. This requirement applies to all facilities producing, processing, or interpreting mammograms, whether for screening or diagnostic purposes. The authority to implement the provisions of the MQSA was delegated by the Secretary of HHS to FDA, which is issuing this interim rule to establish regulations implementing section 354(e) of the PHS Act pertaining to accrediting bodies.

I. Background

The motivation for the MQSA was public response to concerns about breast cancer and to concerns about the quality of mammography services relied on for early detection of breast cancer. Breast cancer is the most prevalent nonskin cancer among women (and the second most deadly), with over 175,000 new cases and 45,000 breast cancer-related deaths occurring annually (Ref. 1). The disease is most treatable in the early stages. Regular screening mammography can often identify possible disease at an early stage, and diagnostic mammography is very valuable in confirming the presence of breast cancer. Current research raises the possibility that widespread use of mammography could reduce breast cancer mortality by approximately one third, especially in older women, through early detection of cancerous lesions and prompt initiation of treatment protocols (Ref. 1). Missed diagnosis of early lesions due to factors such as poor image quality or incorrect interpretation of images could result in delayed treatment, leading to otherwise avoidable increases in mortality or more complex and costly remediations. High-quality mammography procedures are, therefore, vital to ensure that cancerous breast lesions are detected and treated early.

The importance of early detection of breast cancer by screening mammography prompted Congress, in the 1990 Omnibus Budget Reconciliation Act (Pub. L. 101-508), to require that mammography be a covered service for medicare-eligible women. Similarly, various States, under authority of the McCarran-Ferguson Act over private insurance companies, have required that private health insurance carriers and/or the State-administered Medicaid program provide reimbursement for preventive mammography screening services rendered to beneficiaries.

Stimulated by such public health agency programs and public health need, the demand for mammography screening services has increased substantially, resulting in significant growth in the number of mammography facilities, currently estimated to be over 10,000. A concern with respect to this growth is that mammography is one of the more technically challenging radiological procedures, and accurate mammography interpretation is comparatively difficult. Therefore, adequate training of all mammography personnel and programs for quality assurance and quality control are crucial for mammography facilities to attain necessary levels of quality for all mammography services.

However, problems with the provision of quality mammography services have been documented by a number of studies. Significant evidence came from the 1985 Nationwide Evaluation of X-Ray Trends (NEXT) study, a cooperative effort of FDA and the Conference of Radiation Control Program Directors (an organization of State and local radiation control officials). Through the survey of a representative national sample of mammography facilities, the 1985 NEXT study found that the image quality produced by some of these facilities was less than desirable (Ref. 2).

In a 1990 report to Congress, the General Accounting Office (GAO) reported that many mammography service providers lacked adequate quality assurance programs (Ref. 3). GAO concluded that the quality of screening mammography was directly related to whether providers established and maintained a wide range of quality assurance programs. GAO found no relationship between the price charged for screening mammography and adherence to these quality standards. GAO also found evidence that providers performing comparatively larger numbers of mammography examinations were more likely to comply with quality standards, while providers performing relatively few mammograms had the lowest rates of compliance.

Similarly, the American College of Radiology (ACR), a private, nonprofit association of radiologists, investigated the provision of mammography services. In 1987 the ACR began a voluntary Mammography Accreditation Program (MAP), the purpose of which was to provide assurance of quality to patients seeking services at ACR-accredited facilities. The ACR's MAP involves a number of facility procedure and image quality requirements, one of the most significant of which is an evaluation of

clinical mammograms produced by each facility. However, the program at present does not include an on-site inspection of each facility by program personnel. In the absence of a national regulatory requirement, only those facilities that voluntarily sought accreditation have undergone the ACR accreditation process. Nevertheless, the vast majority of mammography facilities have already received (or have applied for) ACR accreditation. Historically, approximately 30 percent of the facilities applying for accreditation fail on their first attempt to meet the ACR Standards, although many of these are subsequently able to improve their services and meet the standards on a second attempt. Over 6,000 facilities, out of the estimated 10,000 facilities in the United States, are currently accredited by the ACR.

A number of States have also instituted quality surveillance, inspection, and licensing programs to ensure that State residents are provided high-quality mammography services. However, many States have not established comprehensive quality assurance standards for mammography. Present State programs typically do not involve a critical examination of the image quality manifested by real clinical mammograms at each facility.

The 1990 Federal legislation that provided coverage under medicare for breast cancer screening (Pub. L. 101–508) (administered by the Health Care Financing Administration (HCFA)) required that facilities seeking reimbursement for screening mammography from medicare meet prescribed quality standards. These standards (set forth in 42 CFR part 494 based on an interim rule published in the Federal Register of December 31, 1990 (55 FR 53510)) apply only to screening mammography, not to diagnostic mammography, and do not provide for image quality examination of clinical mammograms in each facility. Facilities are required to be inspected annually for compliance with the standards. The inspection program began on September 9, 1992. In most States, the inspections are a cooperative effort between the State radiation control agency and the agency that normally conducts medicare inspections under contract with HCFA.

The Breast and Cervical Cancer Mortality Prevention Act of 1990 (Pub. L. 101–354) provided Federal funds to States to ensure that indigent women had access to breast and cervical cancer screening. This statute also required that matching funds be provided by applicant States and that certain quality assurance provisions be met by all covered providers. The Centers for Disease Control and Prevention (CDC), the agency responsible for implementing the program, requires that providers of screening mammography services for their program be accredited by ACR and certified by HCFA, which administers the medicare program.

As indicated above, the lack of uniform national oversight over the wide range of available mammography services has resulted in a patchwork of sometimes overlapping, but frequently less than comprehensive, State and Federal programs for assuring quality mammography. Therefore, on a nationwide level, there are no universal standards for providing safe, reliable, and accurate mammography services. In order to rectify this situation, the MQSA was enacted. Under the MQSA, Congress established a comprehensive statutory mechanism for the certification and inspection of mammography facilities to ensure that, after October 1, 1994, only those facilities which are in compliance with uniform Federal standards for safe high-quality mammography services may legally continue operation. Operation after that date is contingent upon receipt, after application, of an HHS certificate attesting that the facility meets the minimum mammography quality standards promulgated under section 354(f) of the PHS Act. These standards apply to both screening and diagnostic mammography. Specifically, the MQSA requires the following:

1. Accreditation of mammography facilities by private, nonprofit organizations or State agencies which have met the standards established by the Secretary for accrediting bodies and have been approved by the Secretary. The MQSA requires a direct Federal audit of the accrediting bodies through facility inspections by Federal officers. It also requires that, as a part of the overall accreditation process, clinical mammograms from each facility be evaluated for quality.

2. An annual mammography facility physics survey, consultation, and evaluation performed by a certified or State-licensed/approved medical physicist.

3. Annual inspection of mammography facilities, to be performed by Federally-certified or State-certified inspectors. The MQSA requires a Federal audit of the facility inspection program by inspections of a sample of facilities.

4. Establishment of qualification standards for interpreting physicians, mammography technologists, medical physicists, and mammography facility inspectors.

5. Specification of boards or organizations eligible to certify the adequacy of training and experience of particular mammography personnel.

6. Establishment of quality standards for mammography equipment and practices, including quality assurance and quality control programs.

7. Establishment by the Secretary of a National Mammography Quality Assurance Advisory Committee. Among other things, the advisory committee will advise the Secretary on the appropriate quality standards for the mammography facilities and the accrediting bodies.

8. Establishment of standards governing recordkeeping for patient files and requirements concerning mammography reporting and patient notification by physicians.

II. Provisions of the Rule

The MQSA requires the Secretary to set requirements for accrediting bodies and to establish standards for such bodies. The Senate report on the MQSA states that the standards for accrediting bodies must be no less stringent than those established by the ACR (Ref 4.). The legislative history indicates that Congress intended that the ACR program serve as the model for the statutory accrediting body, although Congress also intended that, over time, the accrediting program should undergo improvements stimulated by Federal oversight. Thus, FDA has reviewed the ACR standards and procedures in arriving at the content of this interim rule (Ref. 5). FDA has also reviewed standards and procedures developed by HCFA, a part of the HHS which operates a system of certification for facilities under Medicare (December 31, 1990, 55 FR 53510). Such review has also included relevant State accreditation programs.

On December 14, 1993, the President signed legislation (H. Rept. 2202) granting interim rule authority to the Secretary for promulgation of standards required by the MQSA. This authorization was provided in recognition of the fact that the certification deadline of October 1, 1994, could not be met without streamlining the process for initial promulgation of standards. Granting of this interim rule authority, rather than extension of the deadline to develop standards, was decided upon because of the perceived urgent public health need for Federal standards for mammography. FDA has chosen to use this authority in order to meet the October 1, 1994, deadline for certification of facilities. While FDA believes that there is an urgent need for

standards to be in effect, the agency also wants to provide time for facilities to meet these standards so that they can continue lawfully to operate and so that quality mammography will be available.

Under the interim rule legislation, the Secretary is authorized to issue temporary, interim regulations setting forth standards for approving accrediting bodies and for quality standards for mammography, under section 354(e) and (f) of the PHS Act. Under the abbreviated process, the Secretary is required to adopt existing standards to the maximum extent feasible, such as those established by HCFA, private voluntary accreditation bodies, e.g., ACR, and some States. Also, in developing the interim regulations, the Secretary is not required to consult the National Mammography Quality Assurance Advisory Committee. However, following issuance of the initial standards, Congress intends that the Secretary proceed with the more extensive rulemaking procedures envisioned by the original enactment of the MQSA, including the statutorily required consultation with the Advisory Committee.

Thus, the interim rule authority permits the Secretary to expedite establishment of legally binding initial accreditation and quality standards, based on standards currently in use. These initial standards will be used to accredit and certify facilities before the October 1, 1994 deadline, while the Secretary simultaneously continues to evaluate and develop the final standards under section 354(e) and (f) of the PHS Act. This second set of final regulations, will supersede the initial regulations.

Because these regulations fall short of implementing the entire MQSA, FDA expects, in the future, to propose for notice and comment further implementing regulations not made necessary by section 354(e) and (f) of the PHS Act, such as regulations implementing section 354(r) concerning funding.

The accreditation regulations implemented by this interim rule are consistent with the congressional intent to incorporate existing standards to the maximum extent possible. Significant provisions of the regulations are summarized below.

A. Approval of Accreditation Bodies

Under section 354(e)(1) of the PHS Act (42 U.S.C. 263b(e)(1)), on approval of accrediting bodies, the Secretary is required to do the following:

1. Establish standards requiring accrediting bodies to review clinical images from facilities accredited by those accrediting bodies.

2. Establish standards prohibiting any financial relationship that would constitute a conflict of interest between individuals conducting the clinical image reviews discussed in item 1 above and the facilities undergoing review.

3. Establish standards limiting the imposition of fees by accrediting bodies to reasonable amounts.

4. Establish a requirement that mammography facilities undergo surveys at least annually by a medical physicist and a requirement that monitoring and evaluation of those physicist surveys be conducted by the accrediting body.

5. Establish any necessary additional standards for accrediting bodies beyond those specified by the law.

6. Establish a requirement that accrediting bodies submit to the Secretary information regarding accreditation revocations, denials, and suspensions; changes to the accrediting body standards; and other information that FDA might require. A requirement must also be established that accrediting bodies notify facilities they accredit if their approval as an accrediting body is withdrawn by FDA.

FDA is requiring that, in conducting clinical image reviews, accrediting bodies meet the statutorily defined review frequencies (every 3 years for each facility accredited) and use breast positioning, compression and overall image quality as criteria for clinical image evaluations. FDA notes that because HCFA does not require clinical image review as a condition of certification, facilities that are presently certified only by HCFA would not necessarily qualify for certification by FDA. However, facilities that are accredited by ACR, or an organization with comparable requirements which does require clinical image reviews in addition to other requirements, would qualify for certification by FDA.

Under the statute, potential accrediting bodies are limited to private, nonprofit organizations or State agencies. Therefore, FDA is defining the "reasonableness" of their fees as those limited to recovering costs incurred by the body in accrediting a given facility, including overhead adjusted proportionately for that facility. With regard to reporting and recordkeeping, FDA has established deadlines for accrediting body reports in accordance with suggested intervals in the Senate report accompanying the MQSA. In order to facilitate the certification process, FDA is requiring additional reporting and recordkeeping beyond that specified in the MQSA, including requiring accrediting bodies to collect and submit to FDA the information required for certification under section 354(d)(1) of the PHS Act for all facilities they accredit and also information required for provisional certification. Finally, FDA is requiring that accrediting bodies establish processes for receipt, investigation and records maintenance of complaints about facilities that the bodies accredit and submit to FDA any information requested about facilities they accredit.

In order for an applicant to be approved as an accrediting body, the MQSA requires that applicants establish quality standards for mammography substantially the same as those promulgated under section 354(f) of the PHS Act. The rule provides for FDA review of changes in accrediting body's standards before they go into effect. This is to allow FDA to determine whether a proposed change would so significantly affect the body's standards as to render them no longer "substantially the same as" FDA's standards, which would abrogate the approval of the accrediting organization.

FDA wants to allow flexibility to accrediting bodies to fine-tune standards to their own organizational situation and to make adjustments based on experience. For example, a state might have independent personnel standards to be cross-referenced or otherwise reflected in an accrediting program operated within its borders. To achieve this goal of flexibility, FDA is requiring that accrediting body standards be "substantially the same as" FDA's standards, rather than identical. FDA intends to administer this provision primarily on a section basis. The accrediting body would need to have sections corresponding to each of FDA's, and to achieve a comparable level of quality within each section. Not every provision within a section would need to be identical, but the section could not involve substantially more or less stringent requirements when taken as a whole. Additional standards not fitting within this framework would not be allowed, except as voluntary standards.

FDA anticipates that the standards will require periodic upgrading in response to changes in technology or experience gained in implementing mammography quality programs. If an accrediting body developed a desirable new standard that would be substantially different from existing standards, FDA would expect the body to propose a revision to the FDA standards, which would apply nationally to all accrediting bodies and facilities. FDA would expect to act expeditiously on such proposals. Alternatively, an organization could

create voluntary standards, so long as they did not become binding requirements. With the above three approaches—allowing flexibility for standards to be substantially the same as FDA's, modifying FDA standards over time, and allowing voluntary standards—FDA believes that the desirable flexibility to innovate is preserved without allowing the national quality standards or the integrity of the rulemaking process to be undermined. FDA requests comment on this approach, and on ways to improve it.

Section 354(f)(1)(H) of the PHS Act requires that standards be established relating to special techniques for mammography of patients with breast implants. FDA does not believe that sufficient information is presently available in this area to establish such standards and requests comments on the appropriate contents of such standards for consideration in development of the final rule.

B. Withdrawal of Approval

Section 354(e)(2) of the PHS Act requires the Secretary to promulgate regulations under which the Secretary may withdraw the approval of an accrediting body. Under this section, the Secretary is also required to establish a period of time for which certificates shall continue in effect for facilities accredited by a body whose approval has been withdrawn. The latter requirement is being addressed in subpart B of part 900 (published elsewhere in this issue of the Federal Register) because it pertains to certification. Regarding withdrawal of approval of an accrediting body, FDA has established the following tiered system of enforcement based on the severity of the accrediting body deficiencies identified: (1) Designation of probationary status of the accrediting body, contingent on the development and implementation of a satisfactory corrective action plan for correcting minor deficiencies, and (2) withdrawal of approval of the accrediting body, upon identification of severe accrediting body deficiencies or upon determination that a satisfactory corrective plan of action for minor deficiencies has not been developed or implemented within a specified time period. FDA believes that the agency should only resort to immediate withdrawal of approval of accrediting bodies in cases of very serious deficiencies such as fraud or gross incompetence in the performance of a critical accreditation function. Also, accrediting bodies should be allowed the opportunity to correct minor deficiencies without having their approval withdrawn unless they fail to correct such minor deficiencies in a sufficiently timely manner. FDA will issue notices of opportunity for hearing to accrediting bodies to contest FDA's adverse withdrawal decisions through informal hearings held in accordance with 21 CFR part 16. With regard to placement of an accrediting body on probationary status, FDA is considering whether facilities accredited by such bodies should be notified of the probationary status of the body and solicits comments on this issue for consideration in the development of the final rule. Such notification is not being required in this interim rule.

C. Accreditation and Compliance

Section 354(e)(3) and (e)(4) of the PHS Act require facilities to meet accrediting body standards in order to be accredited and require the accrediting body to take measures, including on-site inspections of a sample of facilities, to ensure that the facilities it accredits meet those standards. Because FDA believes that experience in this aspect of the program is needed before a final requirement is established, FDA has not specified a particular number or percentage of facilities that must be visited annually by the accrediting body; however, FDA is requiring accrediting body applicants to submit information in their applications justifying proposed methods for addressing the inspection requirements of section 354(e)(4) of the PHS Act. This inspection information will be evaluated by FDA in making rulings on applications. FDA has also specified that accrediting bodies must provide facilities the same amount of advance notice of inspection as was recommended in the Senate Report for annual FDA/State facility inspections. FDA believes that this advance notice will not compromise the inspection process and that it is necessary to minimize disruption to the operation of the facility and to the schedules of its patients.

D. Revocation of Accreditation

Section 354(e)(5) of the PHS Act requires the Secretary to establish a time interval for which a facility's certificate will remain in effect if the facility's accreditation is revoked by the accrediting body. This requirement is being addressed in subpart B of this part 900 (published elsewhere in this issue of the Federal Register) because it pertains to certification.

E. Evaluation and Report

Section 354(e)(6) of the PHS Act requires that the Secretary annually evaluate the performance of each approved accrediting body via inspection of facilities accredited by each body and by any additional means the Secretary deems appropriate. In addition to evaluating accrediting bodies via the required inspections, FDA will evaluate accrediting bodies by the following criteria: Clinical image review, phantom image review, speed and efficiency in accrediting facilities, responsiveness to FDA, and recordkeeping. FDA believes that evaluation according to these criteria is necessary because they are important to quality mammography and because they cannot be addressed adequately through facility inspections.

As specifically authorized by the legislation signed by the President on December 14, 1993 (H. Rept. 2202), this interim rule implementing section 354(e) of the PHS Act is being issued without proceeding through the normal notice-and-comment rulemaking process in order to enable FDA to meet the statutory deadline of October 1, 1994, for certification of all certifiable mammography facilities. The agency requests comments on this interim rule. Comments submitted to FDA will be considered in the development of the final rule. Also, the National Mammography Quality Assurance Advisory Committee, which has been chartered, and whose members are in the process of being selected, will be consulted in the development of the final rule in accordance with the requirements of section 354(n) of the PHS Act.

III. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. "The National Strategic Plan for the Early Detection and Control of Breast and Cervical Cancers," U.S. Department of Health and Human Services, 1993.

2. Conway, B. J., J. L. McCrohan, F. G. Rueter, and O. H. Suleiman, "Mammography in the Eighties," *Radiology*, 177:335–39, 1990.

3. "Screening Mammography—Low Cost Services Do Not Compromise Quality," U.S. GAO, GAO/HRD–90–32, January 1990.

4. "Report on the Mammography Quality Standards Act of 1992," U.S. Senate, Report 102–448, October 1, 1992.

5. American College of Radiology, "American College of Radiology Mammography Accreditation Program," July 1993.

IV. Paperwork Reduction Act of 1980

This interim rule contains information collections which are

subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35). The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Requirements for Accrediting Bodies of Mammography Facilities under Pub. L. 102-539—General Requirements.

Description: FDA is issuing an interim rule to implement the accreditation provisions of the MQSA. Under the new law, FDA will accept applications for approval as an accrediting body from private nonprofit organizations or State agencies. This rule establishes procedures for application to FDA as an accrediting body and requirements and responsibilities of such bodies. This action is being taken to ensure adequate and consistent evaluation of mammography facilities on a nationwide basis to help ensure their compliance with quality standards.

As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this interim rule to OMB for its review of these information collection requirements. Other organizations and individuals desiring to submit comments regarding this burden estimate or any aspects of these information collection requirements, including suggestions for reducing the burden, should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attention: Desk Officer for FDA.

ESTIMATED ANNUAL BURDEN FOR REPORTING

CFR Section	No. of respondents	No. of responses per respondent	Total annual responses	Hours per response	Total hours
21 CFR 900.3	6	1	6	60	360
21 CFR 900.4(b)	834	1	834	1	834
21 CFR 900.4(d)	10,000	1	10,000	8	80,000
21 CFR 900.4(e)	1,000	1	1,000	14.5	14,500
21 CFR 900.4(g)	6	1	700	6	4,200
Total					99,894

ESTIMATED ANNUAL BURDEN FOR RECORDKEEPING

CFR section	No. of Recordkeepers	Annual hours per Recordkeeping	Total annual burden hours
21 CFR 900.4(f)	10,000	1	10,000
Total Annual Burden			109,894

V. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Economic Impact

FDA has analyzed together the economic consequences of this rule and the accompanying rule on quality standards. It has tentatively concluded that the pair of rulemakings do not constitute an economically significant rule as defined in Executive Order 12866. It is possible, but not certain, that there will be significant economic effects on a substantial number of small entities. The preamble to the interim rule on quality standards and certification requirements for mammography facilities published elsewhere in this issue of the Federal Register contains a Regulatory Flexibility Analysis dealing with those effects. We welcome comments on both costs and benefits, and on alternatives or options which may be more cost-effective.

VII. Comments

Interested persons may, on or before January 20, 1994, submit to the Dockets Management Branch (address above) written comments regarding this interim rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 900

Electronic products, Mammography, Medical Devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

Therefore, under the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

1. Subchapter I consisting of new part 900 is added to read as follows:

SUBCHAPTER I—MAMMOGRAPHY QUALITY STANDARDS ACT

PART 900—MAMMOGRAPHY

Subpart A—Accreditation

Sec.

Subpart B—[Reserved]

Authority: Secs. 519, 537, and 704(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i, 360nn, and 374(e)); sec. 354 of the Public Health Service Act (42 U.S.C. 263b).

§ 900.1 Scope.

The regulations set forth in this part implement 42 U.S.C. 263b(b) through (f). The intent of subpart A of this part is to establish application procedures for accrediting bodies and to establish requirements and standards for such bodies to ensure that all mammography facilities in the United States are

adequately and consistently evaluated for compliance with quality standards for mammography. The intent of subpart B of this part is to establish procedures for facility certification and to establish quality standards for mammography facilities to assure safe, reliable, and accurate mammography on a nationwide level.

§ 900.2 Definitions.

The following definitions apply to subparts A and B of this part:

(a) *Accrediting body* or *body* means an entity that has been approved by FDA under 42 U.S.C. 263b(e)(1)(A) to accredit mammography facilities.

(b) *Certificate* means the certificate described in 42 U.S.C. 263b(b)(1).

(c) *Certification* means the state of approval of a facility by FDA to provide screening and diagnostic mammography services.

(d) *Clinical image* means a mammogram.

(e) *Facility* means a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility that conducts breast cancer screening or diagnosis through mammography activities, including any or all of the following: The operation of equipment to produce a mammogram, processing of film, initial interpretation of the mammogram, and the viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

(f) *Interpreting physician* means a physician who interprets mammograms made during screening or diagnostic mammography procedures and who meets the requirements of § 900.14(a)(1).

(g) *Mammogram* means a radiographic image produced through mammography.

(h) *Mammography* means radiography of the breast.

(i) *Medical physicist* means a person meeting the qualifications for a medical physicist set forth in § 900.12(a)(3).

(j) *Patient* means any individual who undergoes clinical evaluation in a mammography facility, regardless of whether the person is referred by a physician or is self-referred.

(k) *Phantom* means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

(l) *Phantom image* means a radiographic image of a phantom.

(m) *Provisional certificate* means the provisional certificate described in 42 U.S.C. 263b(c)(2).

(n) *Radiographic equipment* means X-ray equipment used for the production of static X-ray images.

(o) *Radiological technologist* means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and who meets the requirements in § 900.12(a)(2).

(p) *Qualified practicing physician* means a physician meeting the requirements of an interpreting physician as specified under § 900.12(a)(1).

(q) *Survey* means an on-site physics consultation and evaluation of a facility performed by a medical physicist.

§ 900.3 Application for approval as an accrediting body.

(a) *Eligibility.* Private nonprofit organizations or State agencies capable of meeting the requirements of this subpart A may apply for approval as accrediting bodies.

(b) *Application.* One copy of an application for approval as an accrediting body shall be submitted to the Center for Devices and Radiological Health (HFZ–200), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, and should be marked ATTENTION: Mammography Program. Applications for approval as an accrediting body should include the following information:

(1) Name, address, and phone number of body and evidence of nonprofit status (i.e., of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the body is not a State agency;

(2) Standards the body agrees to impose on facilities pursuant to 42 U.S.C. 263b(e)(3);

(3) Methods for performing clinical image review as required in 42 U.S.C. 263b(e)(1)(B)(i)(I);

(4) Methods for monitoring and evaluation of annual surveys of facilities by medical physicists as required in 42 U.S.C. 263b(e)(1)(B)(v);

(5) Methods for performing on-site inspections of facilities as required in 42 U.S.C. 263b(e)(4);

(6) Fee schedules, with supporting cost data; and

(7) Satisfactory assurances that the body will comply with the requirements of § 900.4.

(c) *Ruling on application.* FDA will approve an accrediting body if FDA determines upon review of the application that the body substantially meets (or will substantially meet when it begins to evaluate facilities) the requirements of this subpart, and the body's standards are substantially the same as the quality standards published under subpart B of this part in accordance with 42 U.S.C. 263b(f). If the applicant fails to substantially meet the requirements set forth in this subpart A, or if the applicant's standards are determined not to be substantially the same as the quality standards published under subpart B of this part, or if FDA determines that the applicant has not provided satisfactory assurances that it is capable of meeting the requirements established in this subpart A, FDA will notify the applicant of any problems it has identified with the application and request that the applicant resolve such problems within 90 days of receipt of notice. If the problems are substantially resolved to the satisfaction of FDA within the 90-day time period, the body will be approved as an accrediting body. If the problems are not substantially resolved to the satisfaction of FDA within the 90-day time period, the application for approval as an accrediting body will be rejected and the applicant so notified. A rejected application that has been modified so as to render it satisfactory is subject to resubmission at any time.

§ 900.4 Responsibilities of accrediting bodies.

(a) *Facility standards.* The accrediting body shall require that each facility it accredits meet standards for the performance of quality mammography that are substantially the same as those promulgated in subpart B of this part under 42 U.S.C. 263b(f). The requirements set forth by the body for accreditation of a facility shall address, at a minimum, the following aspects of performing quality mammography:

(1) Physician training, experience, certification, and continuing education;

(2) Technologist training, experience, certification, and continuing education;

(3) Medical physicist training, experience, certification, and continuing education;

(4) X-ray equipment characteristics, including a requirement that the X-ray equipment be specifically designed for mammography;

(5) Quality assurance and quality control programs for ensuring that quality mammography is practiced by the facility;

(6) Phantom image quality testing and objective criteria to be used for passing the image quality test;

(7) Maximum radiation dose for a single view for specific imaging systems;

(8) Information update provisions that require accredited facilities to update at least annually the information listed in this section that they have provided the accrediting body; and

(9) Medical recordkeeping and patient notification requirements.

(b) *Clinical image review.* The accrediting body shall review clinical images from each facility accredited by the body at least once every 3 years and shall also review a random sample of clinical images from each facility accredited by the body in each 3-year period beginning October 1, 1994. These clinical image reviews shall be conducted by a qualified practicing physician not associated with the facility. The clinical image reviews shall ensure that quality clinical images are produced in the facility on a routine basis, as measured by proper breast positioning and compression and overall image quality. Any qualified practicing physicians who conduct clinical image quality reviews shall not have a financial interest in the facilities they review for the accrediting body, nor shall such physicians have any other interest that would constitute an apparent or real conflict of interest, other than receiving a service fee from the accrediting body itself related solely to the work performed in conducting the clinical review.

(c) *Fees.* Fees charged to facilities for accreditation shall be reasonable. FDA will usually find fees to be reasonable if they are limited to recovering costs to the accrediting body, including overhead incurred proportionately in accrediting a given facility. Accrediting bodies may adjust fees annually for inflation in accordance with the Consumer Price Index (CPI).

(d) *Reports of physics survey.* (1) The accrediting body shall require every facility applying for accreditation to submit to the accrediting body, with its accreditation application, a report of a survey by a medical physicist to assess the facility's compliance with the accrediting body's standards established under paragraph (a) of this section. The accrediting body shall require that every facility it accredits undergo an annual survey by a medical physicist to assure continued facility compliance with applicable standards and to provide continued oversight of the facility's quality assurance program. The accrediting body shall require that the results of this survey be transmitted to the accrediting body, together with quality control records and any other information the body may require, as a part of the annual report about the facility.

(2) The accrediting body shall review the report of the annual physicist's survey, the quality control records of the facility, and other information that may come to its attention to determine if all the accrediting body's standards are being met by the facility. If the results of the survey or other information create doubt as to the quality of clinical images produced by the facility, then the accrediting body shall investigate by examination of recent clinical images from that facility to verify that the images meet the evaluation criteria of the accrediting body. If the accrediting body determines that the images are not of sufficient quality, the body shall determine necessary corrective measures to be taken by the facility, establish a schedule for implementation of such measures, and notify the facility that it must implement these measures within the specified schedule in order to retain accreditation. The accrediting body shall verify that the appropriate and necessary steps are taken by the facility within the schedule specified and that all accrediting body standards are being substantially met or will be substantially met. However, the responsibility for compliance remains with the facility.

(e) *On-site inspections.* On an annual basis, in accordance with methods specified in the accrediting body's application for approval, the accrediting body shall make on-site visits to a sufficient number of facilities accredited by the body to assess overall compliance with the accrediting body standards and the quality of performance of mammography. The accrediting body shall prepare and submit one copy of a report of the findings of each of these visits to FDA at the address specified in § 900.3(b). The facility may be given advance notice at the discretion of the accrediting body.

(f) *Complaints.* The accrediting body shall require all facilities it accredits to publish an address where complaints can be filed with the accrediting body, shall investigate such complaints within 90 days of receipt, and shall maintain records of all of such complaints for a period of 3 years from the time of completion of the investigation. Complaint records shall include a summary of the complaint and of the results of the accrediting body's investigation.

(g) *Reporting and recordkeeping.* All reporting requirements listed in this section shall be fulfilled by the accrediting body by sending reports to FDA at the address specified in § 900.3(b). Reports required within 48 hours may be made by phone initially but must be followed by a written notification within 5 days. The accrediting body shall:

(1) Comply with any reporting and recordkeeping requirements specified in paragraphs (a) through (f) of this section;

(2) submit to FDA the names of any facilities for which the accrediting body denies, suspends, or revokes accreditation, and the basis for the action, within 48 hours of the action;

(3) Obtain FDA authorization for any change the accrediting body proposes to make in the standards of the body under § 900.3(c);

(4) collect the information required by 42 U.S.C. 263b(d) for each facility accredited by the body and submit it to FDA within 5 days of the date of accreditation;

(5) accept applications containing the information required in 42 U.S.C. 263b(c)(2) for provisional certificates and in § 900.11(b)(2) for extensions of provisional certificates, on behalf of FDA and notify FDA within 5 working days of the successful completion of the initial application; and

(6) provide to FDA any information requested by FDA about any particular facility accredited by the body within 5 days of receipt of the request.

§ 900.5 Evaluation.

FDA will evaluate annually the performance of each approved accrediting body by:

(a) Inspecting a sample of the facilities accredited by the body and evaluating the reports of inspections to ascertain whether the facilities accredited by the accrediting body are in compliance with the standards promulgated by the agency in subpart B of this part, and

(b) Evaluating a sample of the body's clinical image and phantom image reviews, evaluating the body's speed and efficiency in accrediting facilities, evaluating the body's ability to file reports within deadlines, and reviewing the body's records and recordkeeping processes.

§ 900.6 Withdrawal of approval.

If FDA determines, through the evaluation activities of § 900.5 or through other information that comes to the attention of the agency, that an accrediting body is not in substantial compliance with this subpart, FDA shall initiate enforcement actions as follows:

(a) *Major deficiencies.* If FDA determines that the accrediting body has major deficiencies in performance, such as commission of fraud, or material false statements, or failure to perform a major accreditation function satisfactorily, or significant noncompliance with the requirements of this subpart A, FDA will withdraw its approval of that accrediting body and notify such body of the grounds on which the approval was withdrawn.

(b) *Minor deficiencies.* If FDA determines that the accrediting body has

minor deficiencies in the performance of an accreditation function, including minor failure to comply with this subpart A, FDA will notify the body that it has 90 days to submit to FDA a plan of corrective action addressing the problems specified by FDA. This plan must include a summary of planned corrective actions and a schedule for their implementation.

(1) If the corrective action plan is received within the 90-day time period specified and is satisfactory to FDA, FDA will notify the body that it is on probationary approval status until further notice. This probationary status will remain in effect until such time as the body can demonstrate to the satisfaction of FDA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and the corrective actions taken have substantially eliminated all identified problems. When such determination of restoration of satisfactory performance is made, FDA will restore the body to full approval status.

(2) If the body does not submit a satisfactory corrective action plan within the designated 90-day time period or does not implement an FDA-approved corrective action plan within the time interval specified in the corrective action plan (as amended, with FDA approval, if necessary) FDA will withdraw approval of the body as an accrediting body. In cases of withdrawal of approval of accrediting bodies, if FDA finds that there are satisfactory assurances that the unacceptable performance of the accrediting body has been substantially resolved, on application by the accrediting body, FDA may reinstate the approval of the accrediting body, unless there have been fraud or material false statements.

§ 900.7 Hearings.

Opportunities to challenge final adverse actions taken by FDA regarding approval of accrediting bodies, withdrawal of approval of accrediting bodies, or rejection of a proposed fee shall be communicated through notices of opportunity for informal hearings in accordance with part 16 of this chapter.

Dated: December 9, 1993.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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21 CFR Part 900

[Docket No. 93N-0351]

Quality Standards and Certification Requirements for Mammography Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim rule with request for comments.

SUMMARY: The Food and Drug Administration (FDA) is issuing regulations to implement the Mammography Quality Standards Act of 1992 (the MQSA), which requires the establishment of a Federal certification and inspection program for mammography facilities; regulations and standards for accrediting bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. This rule establishes requirements for certification of mammography facilities, including quality standards for mammography. This action is being taken to assure safe, accurate, and reliable mammography on a nationwide basis. The agency requests comments on the contents of this document.

DATES: These regulations are effective February 22, 1994. Written comments by January 20, 1994. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in 21 CFR 900.12(d)(1)(i), effective February 22, 1994.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Charles K. Showalter, Center for Devices and Radiological Health (HFZ-200), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-3311.

SUPPLEMENTARY INFORMATION:

I. Background

Breast cancer is a leading cause of death among women and is most treatable in the early stages (Ref. 1). Research indicates that, with widespread use of high-quality mammography, breast cancer mortality could be significantly reduced through the identification of early cancerous lesions and early implementation of treatment, especially in older women. However, the quality of mammography at some facilities has been found to be inadequate, resulting in missed diagnosis of early lesions, delayed treatment, and otherwise avoidable increases in mortality (Refs. 2 and 3). Concerns about mammography quality and breast cancer prompted the establishment of various private, State, and Federal programs for assuring quality mammography. Disadvantages of such programs are that they are either voluntary, such as the Mammography Accreditation Program of the American College of Radiology (ACR), or are mandatory but do not apply to all facilities in the United States, such as State programs and programs administered by the Health Care Financing Administration (HCFA). Also, most of these programs lack important mammography quality evaluation criteria or oversight mechanisms, such as clinical image review and on-site inspections of facilities. Therefore, on a nationwide level, there are no universal mandatory standards for providing safe, accurate, and reliable mammography services.

In order to rectify this situation, the MQSA (Pub. L. 102-539) was enacted to establish uniform, national quality standards for mammography. The MQSA amends part F of Title III of the Public Health Service Act (the PHS Act) (42 U.S.C. 262 *et seq.*) by adding new section 354 (42 U.S.C. 263b) to establish a comprehensive statutory mechanism for certification and inspection of all mammography facilities under the regulatory jurisdiction of the United States. Under the MQSA, only those facilities which are in compliance with uniform Federal standards for safe, high-quality mammography services may lawfully continue operation after October 1, 1994. Operation after that date is contingent on receipt, after application, of a certificate from the Secretary of Health and Human Services (HHS) (the Secretary), and by delegation, FDA, that the facility meets the minimum mammography quality standards promulgated under section 354(f) of the PHS Act. This requirement applies to all facilities producing, processing, or interpreting mammograms, whether for screening or diagnostic purposes, except for facilities of the Department of Veterans Affairs.

The authority to implement the MQSA was delegated by HHS to FDA. FDA is issuing this interim rule to establish regulations implementing provisions of section 354(b), (c), (d), (e), and (f) of the PHS Act pertaining to certification procedures and quality standards for mammography. A more detailed legislative history and clinical rationale for this regulation is provided in the preamble for the accreditation

regulations published elsewhere in this issue of the Federal Register.

Specifically, the MQSA requires the following:

1. Accreditation of mammography facilities by private, nonprofit organizations or State agencies which have met the standards established by the Secretary for accrediting bodies and have been approved by the Secretary. The MQSA requires a direct Federal audit of the accrediting bodies through facility inspections by Federal officers. It also requires that, as a part of the overall accreditation process, clinical mammograms from each facility be evaluated for quality.

2. An annual mammography facility physics survey, consultation, and evaluation performed by a certified or State-licensed/approved medical physicist.

3. Annual inspection of mammography facilities, to be performed by Federally-certified or State-certified inspectors. The MQSA requires a Federal audit of the facility inspection program by inspections of a sample of facilities.

4. Establishment of qualification standards for interpreting physicians, mammography technologists, medical physicists, and mammography facility inspectors.

5. Specification of boards or organizations eligible to certify the adequacy of training and experience of particular mammography personnel.

6. Establishment of quality standards for mammography equipment and practices, including quality assurance and quality control programs.

7. Establishment by the Secretary of a National Mammography Quality Assurance Advisory Committee. Among other things, the advisory committee will advise the Secretary on the appropriate quality standards for the mammography facilities and the accrediting bodies.

8. Establishment of standards governing recordkeeping for patient files and requirements concerning mammography reporting and patient notification by physicians.

II. Provisions of the Rule

The MQSA requires the Secretary to set quality standards for certification of mammography facilities. The Senate report on the MQSA states that such standards must be no less stringent than those established by ACR (Ref. 4). The legislative history indicates that Congress intended that the standards established by the ACR program serve as the starting point for quality standards, although Congress also intended that, over time, the standards should undergo improvements stimulated by Federal oversight. Thus, FDA has reviewed the ACR standards and procedures in arriving at the content of this interim rule (Refs. 5 and 6). FDA has also reviewed standards and procedures developed by HCFA, a part of HHS which operates a system of certification for facilities under Medicare (December 31, 1990, 55 FR 53510). FDA's review has also included relevant State accreditation programs.

On December 14, 1993, the President signed legislation (H. Rept. 2202) granting interim rule authority to the Secretary for promulgation of standards required by the MQSA under section 354(e) pertaining to accreditation bodies and under section 354(f) pertaining to quality standards. FDA, in this interim rule, is also establishing some regulations under section 354(b), (c), and (d) because, in FDA's judgment this is necessary for a full implementation of section 354(e) and (f). The interim rule authorization was provided in recognition of the fact that the certification deadline of October 1, 1994, could not be met without streamlining the process for initial promulgation of standards. Granting of this interim rule authority, rather than extension of the deadline to develop standards, was decided on because of the perceived urgent public health need for Federal mammography standards. FDA has chosen to use this authority in order to meet the October 1, 1994, deadline for certification of facilities. While FDA believes that there is an urgent public health need for standards to be in effect, the agency also wants to provide time for facilities to meet the standards so that they can continue lawfully to operate and so that quality mammography will be available.

Under the interim rule legislation, the Secretary is authorized to issue temporary, interim rules setting forth standards for approving accrediting bodies and quality standards for mammography facilities, under sections 354(e) and (f) of the PHS Act. Under the abbreviated process, the Secretary is required to adopt existing standards to the maximum extent feasible, such as those established by HCFA, private voluntary accreditation bodies (e.g., ACR) and some States. Also, in developing the interim rules, the Secretary is not required to consult the National Mammography Quality Assurance Advisory Committee. However, following issuance of the initial standards, Congress intends that the Secretary proceed with the more extensive rulemaking procedures envisioned by the original enactment of the MQSA, including the statutorily required consultation with the Advisory Committee.

Thus, the interim rule authority permits the Secretary to expedite establishment of legally binding initial accreditation and quality standards based on standards currently in use. These initial standards will be used to accredit and certify facilities before the October 1, 1994, deadline, while the Secretary simultaneously continues to evaluate and develop the final standards under section 354(e) and (f) of the PHS Act. This second set of final regulations will supersede the initial regulations.

Because these regulations fall short of implementing the entire MQSA, FDA expects, in the future, to propose for notice and comment further implementing regulations not made necessary by section 354(e) and (f) of the PHS Act, such as regulations implementing section 354(r) concerning funding.

The certification regulations implemented by this interim rule are consistent with the congressional intent to incorporate existing standards to the maximum extent possible. Significant provisions of the certification regulations are summarized below.

A. General

Subpart B of a new part 900 has been established for regulations pertaining to certification of mammography facilities. Section 900.10 of new subpart B sets forth the applicability of certification requirements. As specified by the MQSA, covered facilities include all facilities under the regulatory jurisdiction of the United States that provide mammography services, except facilities of the Department of Veterans Affairs.

B. Requirements for Certification

Section 354(b) of the PHS Act requires that, by October 1, 1994, facilities obtain and prominently display an HHS-issued certificate or provisional certificate in order to: (1) Operate radiological equipment for mammography, (2) provide for processing of film used in mammography (at the facility or elsewhere), and (3) provide for interpretation of mammograms (at the facility or elsewhere). Section 354(c) and (d) of the PHS Act specify application, issuance and renewal requirements for certificates and provisional certificates as follows: certificates may be issued or renewed with an effective period of up to 3 years, and provisional certificates may be in effect for up to 6 months, with a one-time 90-day extension allowance for extenuating circumstances. Also, in section 354(d) of the PHS Act it is

stipulated that applicants for certificates should not be required to provide in an application to the Secretary any information which the applicant has already supplied to the body which accredited the applicant, except as required by the Secretary.

Certification requirements and procedures are set forth in new § 900.11. To implement the certification requirements before the statutory deadline, FDA envisions the likelihood of issuing certificates automatically to facilities already accredited by organizations whose existing accreditation program substantially meets the requirements of subpart A of part 900. For example, ACR would meet these criteria, since the ACR includes the statutorily mandated clinical image review as part of its accreditation process, among other requirements. Therefore, if the ACR applies to FDA for approval as an accrediting body and is so approved, ACR-accredited facilities (over 6,000 of the estimated 10,000 or more facilities in the United States) would qualify for automatic certification. In addition, if, based on their existing standards, other existing accrediting organizations are approved as accrediting bodies by FDA, facilities already accredited by such bodies under such standards would also receive automatic certification. However, in order for any facility to receive automatic certification, it will first be necessary that the body which accredited the facility successfully apply to FDA for approval as an accrediting body in accordance with subpart A of part 900.

Because facilities must be accredited in order to obtain a certificate, FDA provides procedures in new § 900.11(a) for obtaining a list of FDA-approved accrediting bodies. Facilities should note that, because of the concurrent publication of regulations for accreditation and certification, such a list will not be available until such time as FDA receives, evaluates, and rules on applications from potential accrediting bodies.

In keeping with the provision to limit duplicative submission of application information, FDA has established a certificate application system whereby a facility need only submit the statutorily mandated certificate application information to the accrediting body from which it obtained accreditation. In accordance with subpart A of part 900, accrediting bodies will then be required to notify FDA of the names and addresses of facilities they accredit within 5 days of the date of accreditation. FDA will issue certificates to facilities on the basis of such notifications from accrediting bodies, with no further action required on the part of facilities. FDA believes that this is the most efficient means of issuing certificates, eliminating the need for a special FDA application form and minimizing information collection and dissemination requirements.

A similar procedure has been established for provisional certificates. Facilities that have not obtained a certificate by October 1, 1994, but have applied for accreditation from an approved accrediting body will be eligible to receive a provisional certificate. To obtain a provisional certificate, a facility must submit the statutorily mandated application information to the accrediting body from which the facility has applied for accreditation. New facilities may also submit such information directly to FDA. If the accrediting body cannot act on a final certification application by the October 1, 1994 deadline, the accrediting body must then be required to notify FDA of having received an acceptable application, and FDA will issue a provisional certificate on the basis of such notification, with no further action required on the part of the facility. To request an additional 90-day extension to a provisional certificate, prior FDA approval is required because of differing statutory criteria. A facility should submit to the accrediting body a statement of what it is doing to obtain certification and information documenting that a significant adverse impact on the regional availability of mammography would result if such extension was not granted. That information must be forwarded by the accrediting body to FDA, which will determine whether such an extension would be justified.

FDA has designed the certificate issuance and renewal system so that future applications for renewal of certificates will be submitted, received and acted upon steadily over time, rather than all together. Although section 354(c)(1) of the PHS Act allows FDA to issue certificates with an effective period of up to 3 years, FDA believes that to set such an effective period for initial certificates would result in FDA having to process and renew over 10,000 certificates during a short time period within each renewal cycle. To avoid such a situation, FDA has established the expiration date for initial certificates to be 30 days after the expiration date of a facility's existing accreditation, with subsequent certification renewals then having an effective period of 3 years. This system will spread certification renewals over time because the thousands of facilities that are expected to be eligible for automatic certification, as discussed above, were accredited steadily over a period of years. Therefore, under the certification system established, since the expiration of facilities' accreditation is staggered over time, expiration of certificates will be similarly staggered, allowing more efficient use of FDA resources. This system offers the additional advantage for facilities, accrediting bodies, and FDA of closely coupling the accreditation and certification periods.

C. Quality Standards

Section 354(f) of the PHS Act requires the establishment by the Secretary (and by delegation, FDA) of quality standards that facilities must meet in order to become certified. Comparable standards must be adopted and imposed by accrediting bodies in accordance with subpart A of part 900. The quality standards that must be established include: (1) Standards that require establishment and maintenance of a quality assurance and quality control program, which must be overseen by a qualified medical physicist; (2) standards that require use of radiological equipment specifically designed for mammography; (3) requirements for training, licensure, certification and experience of personnel involved with mammography, including interpreting physicians, radiologic technologists, and medical physicists; (4) requirements that facilities maintain mammograms in the permanent medical records of a patient for specified time periods and prepare written reports of the results of any mammogram, as well as communicate those results to the patient in lay terms if the patient has no physician; and (5) standards relating to special techniques for mammography of patients with breast implants.

In § 900.12 of this interim rule, FDA has established standards for personnel, equipment, and practices which are substantially the same as those of the ACR; in fact, FDA has incorporated by reference the ACR's standards for quality assurance and quality control. FDA participated in the development of the ACR standards and believes that they are based on sound scientific principles and clinical judgment gained through extensive experience developing mammography quality assurance practices. The rationale for the ACR standards incorporated in this regulation is provided in a report from the National Council on Radiation Protection and Measurements, which formed the basis for the ACR standards (Ref. 7). FDA believes that the use of the

ACR standards in implementing the MQSA will substantially improve the overall level of mammography quality in the United States, while also allowing FDA to meet the statutory deadlines established by Congress, although FDA believes that improvements in the standards may be necessary over time. FDA solicits comments on what those improvements should be.

For mammography personnel, FDA has established training, certification, education and experience requirements which FDA believes are sufficiently stringent to ensure quality mammography, while allowing needed flexibility to certain organizations with highly mobile personnel, such as the military and Indian Health Service. FDA has also established alternative criteria to the requirements for licensing and certification of medical physicists, in accordance with section 354(f)(1)(E)(iii) of the PHS Act. This provision allows such alternatives in the first 5 years after the date of enactment of the MQSA in order to minimize initial problems with medical physicist shortages that could otherwise arise.

Standards for equipment, dose, quality assurance and quality control are consistent with ACR requirements, and the rationale for these requirements is provided in Ref. 7. Quality assurance and quality control (QA/QC) standards have been addressed partially with an incorporation by reference. FDA has incorporated by reference the most recent ACR QA/QC standards for equipment, rather than develop and codify separate such FDA standards, because, for now, the ACR standards are acceptable without alteration, and the incorporation by reference enables FDA to substantially reduce the volume of material published in the Federal Register and Code of Federal Regulations (CFR). FDA has codified its own standards for other aspects of QA/QC pertaining to phantom images, clinical images, clinical image interpretation, and medical physicist surveys.

Requirements established for reporting and recordkeeping are consistent with the requirements of the PHS Act. As discussed in the regulations for subpart A of part 900, FDA does not believe that sufficient information is presently available with regard to special requirements for mammography of patients with breast implants. FDA requests comments on the appropriate contents of such standards for consideration in development of the final rule for subpart B (and for subpart A).

D. Revocation of Facility Accreditation or Accrediting Body Approval

In accordance with section 354(e)(2) and (e)(5) of the PHS Act, FDA has established regulations in new § 900.13 pertaining to the effects on certification of: (1) Revocation of a facility's accreditation by an accrediting body, and (2) withdrawal of the approval of an accrediting body by the Secretary. In cases of revocation of a facility's accreditation, the facility's certificate will remain in effect until such time as determined by the agency. This will allow the agency to evaluate the basis for revocation and determine what further action may be required, such as an inspection, corrective action plan, or revocation of the facility's certificate. Withdrawal of approval of an accrediting body may have no bearing on the quality of mammography being performed at facilities accredited by that body. Therefore, FDA believes that such facilities should be allowed a reasonable amount of time (1 year) to become reaccredited and recertified, subject to FDA's determination that the facilities continue to perform quality mammography.

As specifically authorized by the legislation signed by the President on December 14, 1993 (H. Rept. 2202), this interim rule implementing section 354(b), (c), (d), (e), and (f) of the PHS Act is being issued without proceeding through the normal notice-and-comment rulemaking process in order to enable FDA to meet the statutory deadline of October 1, 1994, for certification of all certifiable mammography facilities. Comments on this interim rule can be submitted to FDA and will be considered in the development of the final rule. The value of these comments will be enhanced by the extent to which the comments reflect an understanding of the MQSA and support their statements with: (1) Scientific and technical data from the scientific literature and from their own experience, and/or (2) detailed rationale and justification. In addition to considering comments received on this interim rule, the FDA will consult the National Mammography Quality Assurance Advisory Committee (which has been chartered and whose members are in the process of being selected) in the development of final regulations, as required by section 354(n) of the PHS Act.

III. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. "The National Strategic Plan for the Early Detection and Control of Breast and Cervical Cancers," U.S. Department of Health and Human Services, 1993.

2. Conway, B. J., J. L. McCrohan, F. G. Rueter, and O. H. Suleiman, "Mammography in the Eighties," *Radiology*, 177:335–39, 1990.

3. "Screening Mammography—Low Cost Services Do Not Compromise Quality," U.S. GAO, GAO/HRD–90–32, January 1990.

4. "Report on the Mammography Quality Standards Act of 1992," U.S. Senate, Report 102–448, October 1, 1992.

5. American College of Radiology, "American College of Radiology Mammography Accreditation Program," July 1993.

6. American College of Radiology, "Mammography Quality Control: Radiologist's Manual, Radiologic Technologist's Manual, and Medical Physicist's Manual," February, 1992.

7. National Council on Radiation Protection and Measurements, "Mammography—User's Guide," NCRP Report No. 85, August, 1987.

IV. Paperwork Reduction Act of 1980

This interim rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35). The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Quality Standards and Certification Requirements for Mammography Facilities under Pub. L. 102–539—General Requirements.

Description: FDA is issuing an interim rule to implement the certification and quality standards provisions of the MQSA. This rule establishes requirements for certification of mammography facilities, including quality standards for mammography. This action is being taken to assure safe, accurate, and reliable mammography on a nationwide basis.

As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this interim rule to OMB for its review of these information collection requirements. Other organizations and individuals desiring to submit comments regarding this burden estimate or any aspects of these information collection requirements, including suggestions for

reducing the burden, should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, rm. 3208, New Executive Office Bldg., Washington, D.C. 20503, Attention: Desk Officer for FDA.

ESTIMATED ANNUAL BURDEN FOR REPORTING

CFR Section	No. of respondents	No. of responses per respondent	Total annual responses	Hours per response	Total hours
21 CFR 900.11(b)(2)	25	1	25	2	50
Total					50

ESTIMATED ANNUAL BURDEN FOR RECORDKEEPING

CFR Section	No. of recordkeepers	Annual hours per recordkeeping	Total annual burden hours
21 CFR 900.11(c)(1)	1,000	1	1,000
21 CFR 900.12(e)(1)	10,000	1	10,000
Total Annual Burden			11,050

V. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Economic Impact

Executive Order 12866 requires us to assess the costs and benefits of proposed rules. For those rules which have an annual effect on the economy of $100 million or more, or have certain adverse effects on the economy such as a reduction in productivity or competition, a benefit cost analysis must be prepared. We do not believe that these rules are economically significant under the Executive Order criteria. However, the voluntary Regulatory Flexibility Analysis (RFA) presented below covers both benefits and costs. We have complied with other requirements of the Executive Order (e.g., consistency with a statutory mandate, avoidance of interference with State, local, or tribal functions).

The Regulatory Flexibility Act requires us to prepare an RFA if a rule has a significant effect on a substantial number of small entities. For purposes of the act, FDA classifies nearly all mammography facilities as small entities. We do not have sufficient information to determine conclusively whether or not this test is met. Regardless, in the spirit of the act we have prepared the following RFA.

There are approximately 10,000 mammography facilities in the United States. These rules will impose on many of them incremental costs of meeting quality standards relating to personnel, equipment, quality assurance, and medical records.

For purposes of our analysis, we assume that approximately 8,200 facilities already have accreditation or have applied for accreditation and will not incur significant additional costs. Because our interim standards are largely based on and consonant with ACR standards, these facilities should face little additional cost. Moreover, most of these facilities have already been regulated under HCFA rules governing screening mammography under Medicare, and those rules impose similar requirements in a number of areas.

For the remaining 1,800 facilities, we have estimated costs for each substantive requirement (these estimates are available in the Threshold Analysis on file with the docket clerk). In total, we estimate that personnel standards will impose one-time costs of about $2 million, and recurring costs of about $3 million. One-time equipment costs are likely to be about $23 million. Recurring quality assurance costs are likely to total about $19 million. Recurring medical record costs are likely to be about $5 million. In total, the quality standards rule is likely to create one-time costs of about $26 million and recurring costs of about $27 million. Amortizing the one-time costs, the annual cost of the interim rule is about $33 million. Across 1,800 facilities, the average cost will be about $18,000 a year. (A copy of the detailed calculations underlying these numbers is on file with the Dockets Management Branch).

There are 23.5 million mammograms performed annually in the United States, at an average reimbursement of about $100. Total revenues are approximately $2.35 billion, or an average of $235,000 per facility. Thus, expected costs of meeting the quality standards are likely to be about 8 percent of revenues.

In addition, we expect that accreditation costs, borne overwhelmingly by facilities, will be approximately $9 million a year, less than $900 a facility. Most of this cost is due to the requirement for an annual physics survey.

Thus, for those facilities facing involuntary costs, we expect annual costs to average about $19,000 a facility to upgrade under the new regulatory system. Assuming average annual revenues of $235,000, this cost would average about 8 percent of revenues. However, it is possible that this group of facilities may perform fewer mammograms than average, and cost impacts may be proportionately higher. It is also likely that at least some facilities, those with obsolete equipment and low volume, will elect to stop performing mammography rather than upgrade, particularly in areas where there are competing facilities that meet these standards. We do not have any data on likely numbers facing unusually high costs, and welcome comments on the scope and magnitude of such problems.

There are several benefits associated with the uniform national oversight of mammography facilities provided for by this interim rule. First, as discussed in the preamble, research indicates that widespread use of high-quality mammography could significantly reduce breast cancer mortality, especially in older women; however, at some mammography facilities, the quality of service does not permit accurate, reliable detection of early carcinoma. Because the MQSA requires all facilities in the United States to be accredited and to meet quality standards

established by FDA, there should be improvement in the detection rate of early disease. This improvement may be in part due to the clinical image review aspect of the MQSA, which will provide quality monitoring at a level not previously achieved. In addition, by requiring periodic inspections of mammography facilities, the MQSA provides greater assurance of facility adherence to appropriate quality assurance practices.

Improved mammography quality could allow more patients to enjoy the benefits of early detection and thereby reduce the morbidity associated with treating later stage disease. There may also be a reduction in the number of malpractice claims filed for failure to diagnose early breast cancer.

Unfortunately, there are insufficient data available to quantify the potential benefits of the MQSA. Such quantification would require an estimate of the number of lives that could be saved, the number of patients that could be treated at earlier stages, and the number of malpractice claims that could be eliminated as a direct result of the MQSA. The MQSA has a provision for evaluating the functioning and effectiveness of breast cancer screening in the United States, including the role of the MQSA in this process, and such an evaluation will contribute scientific knowledge about these topics. This in turn could contribute quantifiable information about the benefits of the MQSA.

While we do not how have the data that would allow a precise estimate of benefits, their potential magnitude is substantial. For example, if 1 percent of the roughly 13.6 million women screened annually in fact have cancer, if as few as 1 percent of these get false negative results, if these rules could prevent one-half of those false negatives, and if one-fourth of those women's lives could be saved by early treatment, then about 170 lives annually would be saved by these rules. Using any conventional method of valuing lives saved, this would be many times higher than the costs of these regulations. In fact, saving even a handful of lives annually—and we expect far greater effects—would justify the costs of this regulatory approach.

The statute is prescriptive in establishing the new regulatory system. By design, it does not permit a substantially different regulatory approach than the one we have presented. However, it does allow for discretion on details of the individual standards. In devising these standards we sought to avoid unnecessary burden. For example, we allow training and experience, rather than a credential, as qualification for interpreting mammograms. It is possible that there are other changes in details that would either improve the effectiveness of these standards or reduce costs without compromising effectiveness. We welcome comments on any such options and will consider them carefully in revising these rules. We would particularly welcome comment on potential problems for small facilities or for rural areas and on workable solutions for these.

VII. Comments

Interested persons may, on or before January 20, 1994, submit to the Dockets Management Branch (address above) written comments regarding this interim rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 900

Electronic products, Incorporation by reference, Mammography, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 900 is amended as follows:

PART 900—MAMMOGRAPHY

1. The authority citation for 21 CFR part 900 continues to read as follows:

Authority: Secs. 519, 537, and 704(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i, 360nn, and 374(e)); sec. 354 of the Public Health Service Act (42 U.S.C. 263b).

2. New subpart B, consisting of §§ 900.10 through 900.14, is added to read as follows:

Subpart B—Quality Standards and Certification

Sec.

Subpart B—Quality Standards and Certification

§ 900.10 Applicability.

The provisions of this subpart are applicable to all facilities under the regulatory jurisdiction of the United States that provide screening and/or diagnostic mammography services, with the exception of facilities of the Department of Veterans Affairs.

§ 900.11 Requirements for certification.

(a) *General.* After October 1, 1994, a certificate issued by FDA will be required for lawful operation of all facilities. In order to obtain a certificate from FDA, facilities are required to meet the quality standards in § 900.12 and to be accredited by an accrediting body approved by FDA. On request from a facility, FDA will provide such facility with a current list of approved accrediting bodies. Any request for such list shall include the name and address of the facility and must be sent to the address provided in § 900.3(b).

(b) *Application*—(1) *Certificates.* When applying for accreditation to an approved accrediting body, a facility shall submit to such accrediting body the information required in 42 U.S.C. 263b(d)(1). If and when the facility becomes accredited, information required for certification of the facility shall be forwarded to FDA by the accrediting body, in accordance with § 900.4(g)(4).

(2) *Provisional certificates.* Facilities that have not obtained a certificate by October 1, 1994, but have applied for accreditation to an approved accrediting body by then are eligible to receive a provisional certificate. To receive a provisional certificate, a facility shall submit the information required in 42 U.S.C. 263b(c)(2) to an approved accrediting body. New facilities may also submit such information directly to FDA. If and when the accrediting body determines that such application is sufficiently complete for review purposes, this fact shall be communicated to FDA by the accrediting body in accordance with § 900.4(g)(5). To apply for a 90-day extension to a provisional certificate, a facility shall submit to the accrediting body a statement of what the facility is doing to obtain certification and evidence that a significant adverse impact on the regional availability of mammography would result if such facility did not obtain an extension. Such information shall be forwarded to FDA by the accrediting body in accordance with § 900.4(g)(5).

(c) *Issuance and renewal of certificates*—(1) *Certificates.* FDA will issue a certificate to a facility within 30 days of receipt of notification from an approved accrediting body of the accreditation of such facility. The initial certificate for a facility shall remain in effect until 30 days after the date of expiration of the facility's existing

accreditation unless certification and/or accreditation of the facility is revoked prior to such deadline. FDA will issue a renewed certificate to a previously certified facility within 30 days of receipt of notification from an approved accrediting body of renewal of the accreditation of such facility. A renewed certificate shall be effective for a period of 3 years from the date of issuance, unless certification and/or accreditation of the facility is revoked prior to such deadline.

(2) *Provisional certificates.* FDA will issue a provisional certificate to a facility within 10 days of receipt of notification from an approved accrediting body of satisfaction of the requirements of paragraph (b)(2) of this section. A provisional certificate shall be effective for 6 months from the date of issuance. FDA will issue a 90-day extension for a provisional certificate within 10 days of receipt from the accrediting body of the information required in paragraph (b)(2) of this section, provided that FDA determines that the statutory prerequisites for the extension as set forth in section 354(c)(2) of the Public Health Service Act have been met. No renewal of a provisional certificate beyond the 90-day extension can occur.

§ 900.12 Quality standards.

The following requirements establish the minimum quality standards that must be met by a facility to be eligible for certification to provide screening and/or diagnostic mammography services:

(a) *Personnel.* The following requirements apply to personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities. Lists of personnel certifying bodies approved by FDA and referenced in this section may be obtained by submitting to FDA at the address specified in § 900.3(b) a request containing the information needed and the name and address of the facility.

(1) *Interpreting physician.* Interpreting physicians shall meet the following requirements:

(i) Be licensed to practice medicine in the State or facility in which they are practicing; and

(ii) Have the following training:

(A) Be certified by one of the bodies approved by FDA to certify interpreting physicians; or

(B) Have had at least 2 months of documented full-time training in the interpretation of mammograms, including instruction in radiation physics, radiation effects, and radiation protection; and

(C) Have 40 hours of documented continuing medical education in mammography. Time spent in residency specifically devoted to mammography will be accepted, if documented in writing by the radiologist; and

(iii) Have the following initial experience:

(A) Have read and interpreted the mammograms from the examinations of at least 240 patients in the 6 months preceding application; or

(B) Read and interpret mammograms as specified in paragraph (a)(1)(iii)(A) of this section under the direct supervision of a fully qualified interpreting physician; and

(iv) Have the following continuing experience:

(A) Continue to read and interpret mammograms from the examination of an average of at least 40 patients per month over 24 months; and

(B) Continue to participate in education programs, either by teaching or completing an average of at least five continuing medical education credits in mammography per year.

(2) *Radiological technologist.* Radiological technologists shall meet the following requirements:

(i) Have a license to perform radiographic procedures in the State or facility where they are practicing; or

(ii) Have certification by one of the bodies approved by FDA to certify radiologic technologists; and

(iii) For those radiological technologists associated with facilities applying for accreditation before October 1, 1996:

(A) Have undergone training specific to mammography, either through a training curriculum or special mammography course, and accumulate at least an average of five continuing education units per year related to mammography; or

(B) Have 1 year of experience in the performance of mammography and by October 1, 1996, meet the training requirements of paragraph (a)(2)(iii)(A) of this section; and

(iv) For those radiological technologists associated with facilities applying for accreditation on and after October 1, 1996, meet the requirements of paragraph (a)(2)(i) or (a)(2)(ii) of this section and undergo specific training in mammography through documented curriculum and on-the-job training under the direct supervision of experienced mammographers; and

(v) Participate in formal continuing education programs and accumulate an average of at least five continuing education units in mammography per year.

(3) *Medical physicist.* Medical physicists shall meet the following requirements:

(i) Have a license or approval by a State to conduct evaluations of mammography equipment and procedures as required under the Public Health Service Act; or

(ii) Have certification in an accepted specialty area by one of the bodies approved by FDA to certify medical physicists; or

(iii) For those medical physicists associated with facilities applying for accreditation before October 27, 1997, meet the following criteria:

(A) Have a masters, or higher, degree in physics, radiological physics, applied physics, biophysics, health physics, medical physics, engineering, radiation science, or in public health with a bachelor's degree in the physical sciences; and

(B) Have 1 year of training in medical physics specific to diagnostic radiological physics; and

(C) Have 2 years of experience in conducting performance evaluation of mammography equipment; and

(iv) Participate in continuing education programs related to mammography, either by teaching or completing an average of at least five continuing education units per year.

(b) *Equipment*—(1) Radiographic equipment designed for conventional radiographic procedures that have been modified or equipped with special attachments for mammography shall not be used for mammography.

(2) Radiographic equipment used for mammography shall:

(i) Be certified pursuant to § 1010.2 of this chapter as meeting the applicable requirements of §§ 1020.30 and 1020.31 of this chapter in effect at the date of manufacture;

(ii) Be specifically designed for mammography;

(iii) Incorporate a breast compression device; and

(iv) Have the provision for operating with a removable grid, except for xeromammography systems.

(c) *Dose.* The average glandular dose delivered during a single cranio-caudal view of an accepted phantom simulating a 4.5 centimeter thick, compressed breast consisting of 50 percent glandular and 50 percent adipose tissue, shall not exceed 3.0 milliGray (0.3 rad) per exposure for screen-film mammography procedures and 4.0 milliGray (0.4 rad) per exposure for xeromammography procedures. The dose shall be determined at least annually under the technique factors and conditions that

are used to produce the phantom images submitted for accreditation.

(d) *Quality assurance*—(1) *Equipment.* Each facility shall establish and maintain a quality assurance program to assure the adequate performance of the radiographic equipment and other equipment and materials used in conjunction with such equipment sufficient to assure the reliability and clarity of its mammograms. The program shall also require periodic monitoring of the dose delivered by the facility's examination procedures to ensure that it does not exceed the limit specified in paragraph (c) of this section and is appropriate for the image receptor used. Such quality insurance program shall:

(i) For screen-film systems, be substantially the same as that described in the 1992 edition of "Mammography Quality Control: Radiologist's Manual, Radiologic Technologist's Manual, and Medical Physicist's Manual," prepared by the American College of Radiology, Committee on Quality Assurance in Mammography, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American College of Radiology, Mammography Accreditation Program, 1891 Preston White Dr., Reston, VA 22091–5431; and may be inspected at the Center for Devices and Radiological Health, Division of Mammography and Radiation Programs (HFZ–200), 5600 Fishers Lane, Rockville, MD 20857; or may be examined at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC; or

(ii) For systems with alternate image receptor modalities, be substantially the same as the quality assurance program recommended by the image receptor manufacturer, which, if followed, will allow a facility to maintain high image quality; and

(iii) For all image receptors, provide for the maintenance of log books documenting compliance with the applicable requirements in paragraph (d)(1) of this section and recording corrective actions taken.

(2) *Phantom images.* Each facility shall establish and maintain a program to assess the performance of the mammography system through the evaluation of radiographic images obtained with a phantom. The phantom must be of a type approved or accepted by the American College of Radiology or of an equivalent type accepted by FDA. The phantom images must score at least the minimum required by the accrediting body.

(3) *Clinical images.* Each facility shall establish and maintain a clinical image quality control program, including:

(i) Monitoring of mammograms repeated due to poor image quality; and

(ii) Maintenance of records, analysis of results, and a description of any remedial action taken on the basis of such monitoring.

(4) *Clinical image interpretation.* Each facility shall establish a system for reviewing outcome data from all mammography performed, including followup on the disposition of positive mammograms and correlation of surgical biopsy results with mammogram reports.

(5) *Surveys.* As a part of its overall quality assurance program, each facility shall have a medical physicist establish, monitor, and direct the procedures required by paragraphs (d)(1), (d)(2), and (d)(3) of this section and perform a survey of the facility to assure that it meets the quality control and equipment standards as specified in paragraph (b)(2) of this section. Such surveys shall be performed at least annually, and reports of such surveys shall be prepared and transmitted to the accrediting body in accordance with § 900.4(d)(1). Each such report shall be retained by the facility until such time as the next annual survey is satisfactorily completed.

(e) *Medical records.* (1) Each facility shall maintain mammograms and associated records in a permanent medical record of the patient as follows:

(i) For a period of not less than 5 years, or not less than 10 years, if no additional mammograms of the patient are performed at the facility, or longer if mandated by State or local law; or

(ii) Until requested by the patient to permanently transfer the records to a medical institution, or to a physician of the patient, or to the patient herself, and the records are so transferred.

(2) Each facility shall prepare a written report of the results of any mammography examination. Such report shall be completed as soon as reasonably possible and shall:

(i) Be signed by the interpreting physician; and

(ii) Be provided to the patient's physicians (if any); or

(A) If the patient's physician is not available or if the patient does not have a physician, the report shall be sent directly to the patient; and

(B) If such report is sent to the patient, it shall include a summary written in language easily understood by a lay person; and

(iii) Be maintained in the patient's record in accordance with paragraph (e)(1) of this section.

§ 900.13 Revocation of accreditation and accrediting body approval.

(a) *Accreditation.* If a facility's accreditation is revoked by an accrediting body, the facility's certificate shall remain in effect until such time as determined by the agency on a case-by-case basis after an investigation into the reasons for the revocation. If FDA determines that the revocation was justified by violations of applicable quality standards, FDA will revoke or suspend the facility's certificate and/or require the submission and implementation of a corrective action plan, whichever action will protect the public health in the least burdensome way.

(b) *Accrediting body approval.* If the approval of an accrediting body is revoked by FDA, the certificates of the facilities accredited by such body shall remain in effect for a period of 1 year after the date of such revocation subject to FDA's determination that the facility continues to perform quality mammography. By the end of a year following revocation of approval of a facility's accrediting body, the facility must obtain accreditation by another accrediting body.

§ 900.14 Hearings regarding certification decisions.

Opportunities to challenge final adverse actions taken by FDA regarding denials of certification or suspension or revocations of certification of facilities will be communicated through notices of opportunity for informal hearings in accordance with part 16 of this chapter.

Dated: December 10, 1993.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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